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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,697	04/17/2007	Francis Scott Corey		5413

7590 09/17/2008  
OBER, KALER, GRIMES & SHRIVER  
ATTORNEYS AT LAW  
120 EAST BALTIMORE STREET  
BALTIMORE, MD 21202-1643

EXAMINER
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SHAH, SAMIR M

ART UNIT	PAPER NUMBER
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2856

MAIL DATE	DELIVERY MODE
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09/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/580,697

**Applicant(s)**

COREY ET AL.

**Examiner**

SAMIR M. SHAH

**Art Unit**

2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CD/CD)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "22" has been used to designate, "contoured pocket" (figures 1, 11, 13 and 14), "sealing rings" (figures 6-9), "sampling chamber" (specification, page 24, line 16) and "port" (specification, page 24, line 16).
3. Figure 8(d), mentioned in the specification, on page 24, line 22 and on page 25, line 7, is not in the drawings.
4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as

either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

5. The disclosure is objected to because of the following informalities:
  - (a) As to page 23, lines 8 and 11, delete "chamber 326" and replace it with --chamber 325--.
6. Appropriate correction is required.

### ***Claim Objections***

7. Claims 1, 3, 5, 8, 9, 11 and 17 are objected to because of the following informalities:
  - (a) As to claim 1, line 9, delete "said transducer(s)" and replace it with --said at least one transducer--.
  - (b) As to claim 3, line 3, delete "a blood sample" and replace it with --the blood sample--.
  - (c) As to claim 5, line 2, delete "pivoting door" and replace it with --a pivoting door--.
  - (d) As to claim 8, line 3, delete "slidable carriage" and replace it with --a slidable carriage--.

- (e) As to claim 9, line 2, delete "controlled-unlatching" and replace it with --controlled unlatching--.
  - (f) As to claim 11, 2<sup>nd</sup> to last line, delete "processor" and replace it with --a processor--.
  - (g) As to claim 17, line 2, delete "A disposable" and replace it with --a disposable--.
8. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 6, 11, 14, 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- (a) Claim 1 recites the limitation "said pulse generator" in the 8<sup>th</sup> line. There is insufficient antecedent basis for this limitation in the claim.
- Is "pulse generator" referring to "signal generator" recited in the 7<sup>th</sup> line of the claim?

(b) Claim 6 recites, "said door is spring-biased open" in the last line. It is not clear what exactly is being referred to by this limitation. Is the "door" spring-biased and further in an open condition? Is the door open due to a biased spring?

(c) Claim 11 recites the limitation "said analyzer" in the 8<sup>th</sup> line. There is insufficient antecedent basis for this limitation in the claim.

Is "analyzer" referring to the "apparatus for determining hematocrit or hemoglobin concentration of blood" recited in the 1<sup>st</sup> two lines of the claim?

(d) Claims 14 and 15 recite the limitation "said bulb" in the 1<sup>st</sup> line. There is insufficient antecedent basis for this limitation in the claim.

Is claim 13 intended to be dependent on claim 12, which recites "a bulb" in the 2<sup>nd</sup> line?

(e) Claim 17 recites "an analyzer" in the 4<sup>th</sup> line and "an analyzer unit" in the 5<sup>th</sup> line. Are these two limitations distinct from each other? Are "analyzer" and "analyzer unit" referring to the exact same component?

(f) Claim 17 recites the limitation "said measured physical parameter" in the last line. There is insufficient antecedent basis for this limitation in the claim.

***Allowable Subject Matter***

11. Claims 1, 11 and 17 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

12. Claims 2-10, 12-16 and 18-20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

### ***Reasons for Allowance***

13. The following is an examiner's statement of reasons for allowance:

(a) As to claims 1-10 and 18-20, the prior art does not expressly disclose or provide motivation to combine a system for determining hematocrit or hemoglobin concentration of blood with an analyzer for receiving a sampling device for collecting blood, with at least one ultrasonic transducer oriented toward an aperture in the sampling device for emitting an ultrasonic signal into the blood sample while still inside the sampling device.

(b) As to claims 11-16, the prior art does not expressly disclose or provide motivation to combine an apparatus for determining hematocrit or hemoglobin concentration of blood by ultrasonic analysis that includes a sampling device for acquiring a blood sample having a finger-grip at one end and an opposing functional end that includes a collecting region for collecting by capillary action, and a testing region and a pumping region.

(c) As to claim 17, the prior art does not expressly disclose or provide motivation to combine a blood analysis device for ultrasonically analyzing blood including a disposable blood sampling device that collects a sample by capillary action, and a means for transferring the blood to a testing cell by pressure differential.

(d) The closest prior art reference, Brimhall et al. (US Patent 4,854,170 henceforth "Brimhall") discloses an "apparatus and method for using ultrasound to determine hematocrit" including a sampling device/capillary tube (12) for collecting a blood sample (20), an analyzer, a signal/frequency generator (16) for generating an electronic signal, at least one ultrasound transducer (14) coupled to the generator (16) for converting the electronic signal to an ultrasonic signal, a receiver and a processor (figures 1-3; column 3, line 37 - column 4, line 36).

However, Brimhall does not disclose or provide motivation to combine with the prior art, the above-mentioned respective limitations in claims 1-20, respectively.

14. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***



15. The prior art made of record and not relied upon, cited in the attached 892 form, is considered pertinent to applicant's disclosure.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMIR M. SHAH whose telephone number is (571)272-2671. The examiner can normally be reached on Monday-Friday 10:00 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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